

REMARKS

The needed changes in the specification are made herewith.

The claims previously in the case are replaced by a set of new claims that are believed to be proper as to form and clearly patentable over the cited references.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as being unpatentable over COUGOULIC in view of LAYROLLE et al., or further in view of ELLINGSEN et al. or CARR.

COUGOULIC discloses a material made of 65% to 90% by weight of a biocompatible binder and 10% to 35% by weight of at least one compound for adding calcium and phosphorus.

LAYROLLLE et al. describes a medical device, such as an orthopaedic or dental prosthesis, covered by a coating intended to optimize the biocompatibility and/or the bioactivity of said medical material.

The material described comprises a matrix made of an inorganic, metallic or organic material.

This matrix is coated with a final layer allowing the deposit of inorganic ions and of one or more bioactive agents, that under aseptic conditions obviate subsequent sterilization operations (paragraph 8).

The bioactive agents in question are for example peptides or proteins, such as growth factors (paragraph 28) or growth hormones (paragraph 30).

Preferably, this final layer is applied on a "pre-coat" of inorganic compound, comprising for example calcium and phosphorus, previously applied on the matrix (paragraph 25).

To optimize the adhesion of the final layer or the pre-coat, the matrix could be previously treated by different surface pickling treatments (paragraphs 22 and 23).

Moreover, the matrix uncoated or coated with the pre-coat, can be treated by a sterilization treatment, in particular by autoclaving under steam (paragraph 24).

As a result, in a general way, the integration characteristics are optimized in LAYROLLE et al., by the applying a final layer of inorganic ions and of one or more bioactive agents.

Moreover, in LAYROLLE et al., it appears clearly that the surface pickling operations are performed on the matrix, in all the cases before the deposit of the pre-coat or the final layer.

This surface pickling operation aims only at optimizing the adhesion of the coatings to the reception matrix (paragraph 21 and 22).

In all the cases, the matrix, coated by the pre-coat, may be subjected to a sterilization operation, but which does not have any pickling effect.

In accordance with new claim 21, the material of the present invention is distinguished from that of COUGOULIC by the fact that it comprises a surface having micro-pores through which emerges the compound for adding calcium and phosphorus.

Indeed, in practice, it has been discovered that the molded material described in COUGOULIC has a surface composed mainly of the biocompatible binder (which does not have such micro-pores through which emerges the compound for adding calcium and phosphorus).

The inventor showed that the surface of the material in accordance to the invention, is interesting in that it confers some particularly interesting integration characteristics to the surrounding tissue, better than these of the material not having such micro-pores through which emerges calcium/phosphorus.

The particular surface of the material allows direct access of the bone cells to the calcium/phosphorus components.

Moreover, in practice, after implantation into the bone, the surrounding tissues remove the emerging calcium/phosphorus components, which create holes at the surface of the material then colonized by said tissues.

This phenomenon contributes to optimal integration of the material into the surrounding tissues.

The material of the invention may be used in the medical or veterinary field, and can be obtained in particular by the production process of which the main characteristics are specified in new claim 28.

The technical problem for one skilled in the art would thus be to optimize the integration characteristics in the surrounding tissue, of the molded material described in the closest prior art, namely, COUGOULIC.

If one skilled in the art sought to optimize the integration characteristics of the material described in COUGOULIC in view of LAYROLLE et al., he/she would thus at the most be encouraged to apply a final layer of inorganic ions and of one or more bioactive agents on the molded material.

However, the product thus obtained would be basically different from the one now specified in the new claim 21, in that it would not comprise any micro-pores through which the compound for adding calcium and phosphorus could emerge (because of the above mentioned final layer).

For this reason, new claim 21 should be regarded as inventive: one skilled in the art would not have any reason for a molded piecework to create micro-pores through which emerge calcium/phosphorus components, in order to optimize its integration characteristics.

As to new basic method claim 28, one skilled in the art would not have any reason to practice the surface pickling

treatment of LAYROLLE et al., on the material described in COUGOULIC to optimize the integration.

Indeed, as specified hereabove, in LAYROLLE et al., there is always applied a pickling treatment on the un-coated matrix, i.e. not coated by the pre-coat or the final layer. This is explained by the fact that this treatment has for its only function to optimize the coating adhesion of the surface coatings to the matrix.

Only the sterilization operations, which have no pickling effect, are applied to the coated matrix.

Moreover, the thickness of the pre-coat and of the final layer being very thin (about ten or so micrometers; see in particular paragraph 86), the performance of a pickling treatment thereon would damage it significantly.

For these reasons, here also, no teaching of LAYROLLE et al. would suggest to one skilled in the art to perform a surface pickling treatment on the molded material described in COUGOULIC to optimize its integration, while this pickling treatment in LAYROLLE et al. is performed solely to ensure an optimal coating adhesion.

But even if one skilled in the art were to perform this surface pickling treatment on the COUGOULIC material, he/she would apply then also at least the final layer of LAYROLLE et al.

The product obtained by this process would then be, here again, very different from that of new claim 28, since the micro-pores obtained would be covered by said final layer.

Thus, new basic claim 28, like new basic claim 21, recites unobvious and hence patentable subject matter.

The tertiary references to ELLINGSEN et al. and CARR may teach the features for which they were applied; but as neither of these improves the rejection on COUGOULIC in view of LAYROLLE et al., discussed above, it is not believed to be necessary to discuss these tertiary references in further detail at this time.

As the claims now in the case bring out these novel and unobvious aspects of the present invention with ample particularity and distinctness, it is believed that they are all patentable, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional  
fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

A handwritten signature in black ink, appearing to read 'R. J. Patch', written over a horizontal line.

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